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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/309,038	05/10/1999	PETER BERNARD HEIFETZ	A-30496B	7012

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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/309,038

Applicant(s)

HEIFETZ ET AL.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,5-12,16-30,34-40,47,49,56,58,62,73 and 76-86 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5-12,16-30,34-40,47,49,56,58,62,73 and 76-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection to claim 46 is withdrawn in light of its cancellation.
3. The rejection of claims 4-12, 16-30, 34-40, 46, 47, 49, 50, 52, 56-58, 60, 62, 73, and 76-85 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, are withdrawn in light of the claim amendments or cancellations.

#### *Claim Rejections - 35 USC § 112*

4. Claims 47, 49, 56, 58, and 86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 47, 49, 56, 58, and 86: the claims depend from claim 46 or 60, which are cancelled.

In claim 56: the recitation, "Seeds regenerated from the plant" renders the claim indefinite. It is not clear what is meant by a seed that is regenerated from a plant.

In claim 62: the recitation, "said cell further comprises a sense RNA fragment and an antisense RNA fragment of said viral genome or portion thereof" renders the claim indefinite. It is not clear if this is meant to be the same fragments mentioned in claims 1 and 8.

5. Claims 1, 5-12, 16-30, 34-40, 62, 73, and 76-85 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed August 12, 2003. Applicants traverse in the paper submitted February 11, 2004. Applicants' arguments were fully considered but were not found persuasive.

Applicants argue the BNYVV nucleotide sequence was available in the prior art, and cite Bouzoubaa et al. and GenBank Accession No. D00115 (response, page 9, 3<sup>rd</sup> full paragraph). Applicants admit that the BNYVV RNA1 sequence GenBank was replaced in 2002 (response, page 9, 3<sup>rd</sup> full paragraph). As this revised sequence was not available to one skilled in the art on the filing date of the instant application, the GenBank sequence cannot be relied upon to satisfy written description. The claims recite specific nucleotide sequences of BNYVV RNA1, and Example 9 of the specification cites the GenBank sequence as the source of the viral nucleotide sequence. It is suggested that the sequence of BNYVV RNA1 as it appeared on the filing date of the instant application, be submitted as part of the sequence listing, and the specification in Example 9 and claim 82 be amended to recite the corresponding sequence identifier. A statement should also be submitted by Applicants indicating that the sequence is that which appeared in GenBank Accession No. D00115 at the time the invention was filed.

Regarding the lower size limit of the RNA fragments of the claimed invention, Applicants argue that the claims have been amended to recite the lower limit of 21 nucleotides

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(response, page 9, 4<sup>th</sup> full paragraph). Applicants indicate that support is found on page 42, 3<sup>rd</sup> paragraph of the specification and Voinnet et al. (response, page 8, 3<sup>rd</sup> full paragraph). However, the specification does not provide support for the recitation, "at least 21 nucleotides in length." The specification also does not mention Voinnet et al. This recitation is NEW MATTER and must be removed from the claims.

Applicants submit a declaration under 37 CFR 1.132, signed by Dr. Ian Evans, an employee of the assignee of the instant invention. Applicants argue that the declaration describes work conducted as described in the specification, to produce plant cells resistant or with improved tolerance to a tospovirus, potyvirus, and cucomovirus (response, page 9, last two paragraphs). However, this declaration does not address the issues discussed above.

The rejection is withdrawn from claims 47, 49, 56, and 58, as these claims depend from a cancelled claim. Claims 4, 50, 52, 57, and 60 are cancelled.

6. Claim 81 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed August 12, 2003. Applicants traverse in the paper submitted February 11, 2004. Applicants' arguments were fully considered but were not found persuasive for claim 81.

Applicants argue that the claims have been amended to correct typographical and mathematical errors, and to remove the recitation, "about" (response, page 11, 1<sup>st</sup> full paragraph).

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However, claim 81 recites "about 450" nucleotides. There is no recitation of "about 450" nucleotides in the specification. The recitation still constitutes NEW MATTER and must be removed from the claim.

7. Claims 1, 5-12, 16-30, 34-40, 62, 73, and 76-85 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed August 12, 2003. Applicants traverse in the paper submitted February 11, 2004. Applicants' arguments were fully considered but were not found persuasive.

Applicants argue that Example 9 in the specification describes the use of sequences from a furovirus (BNYVV) for producing plants with resistance to a furovirus (response, page 10, 3<sup>rd</sup> and 5<sup>th</sup> full paragraphs). As discussed above, Example 9 indicates that the BNYVV sequences was from "accession no. D00115", and Applicants admit that the sequence in this GenBank entry was revised after the filing date of the instant application. The revised sequence in this database entry cannot be relied upon as support for enablement. As discussed above, Applicants also indicated that a BNYVV RNA1 nucleotide sequence is also disclosed in Boubouzaa et al. However, the specification does not cite this publication and only cites the database entry. It is again suggested that the sequence of BNYVV RNA1 in GenBank Accession No. D00115, as it appeared on the filing date of the instant application, be submitted as part of the sequence listing, and the specification in Example 9 and claim 82 be amended to recite the corresponding

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sequence identifier. A statement should also be submitted by Applicants indicating that the sequence is that which appeared in GenBank Accession No. D00115 at the time the invention was filed.

Regarding the issue concerning the enablement of the portion of the viral RNA fragments, Applicants argue that claims 1 and 12 have been amended to recite that RNA fragments are at least 21 nucleotides in length (response, page 10, 6<sup>th</sup> full paragraph). However, Applicants admit, in Exhibit 3 (submitted with the declaration), that the smallest fragment sufficient for resistance is 150 nucleotides. Applicants have not enabled the claimed invention using portions of viral genomes as small as 21 nucleotides. In light of Applicants' admittance, undue experimentation would be required by one skilled in the art to make and use RNA fragments as small as 21 nucleotides in length to confer resistance to plants against a furovirus, potyvirus, tospovirus, or cucumovirus.

***Claim Rejections - 35 USC § 103***

8. Claims 1, 5-12, 16-30, 34-40, 62, 73, and 76-85 remain rejected under 35 U.S.C. 103(a), for the reasons of record stated in the Office action mailed August 12, 2003. Applicants traverse in the paper submitted February 11, 2004. Applicants' arguments were fully considered but were not found persuasive.

Applicants argue Fire et al. describe in the examples the microinjection of RNA into nematodes. Applicants argue that Fire et al. do not provide a reasonable expectation of success of using a double stranded RNA synthesized from a DNA construct, and fails to provide any working example of such a plant. Applicants argue that additional references, alone or in

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combination with Fire et al., do not make obvious or provide a reasonable expectation of success of the present invention (page 12, 2<sup>nd</sup>-4<sup>th</sup> full paragraphs). However, Applicants do not provide any explanation as to why they believe that the prior art fails to teach that RNA can be synthesized from a DNA construct. Further, instant claims 1-11 and 62 do not require any DNA construct. The claims of Fire et al. indicate that the cell in which the method is used is from a plant cell. Therefore Fire et al. does enable practice of the method in plant cells. Issued patents are presumed valid. See 35 U.S.C. 282. The rejection is withdrawn from claims 47, 49, 56, and 58, as these claims depend from a cancelled claim. Claims 4, 50, 52, 57, and 60 are cancelled.

### *Summary*

9. Claims 1, 5-12, 16-30, 34-40, 47, 49, 56, 58, 62, 73, and 76-86 are rejected.
10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,



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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 6, 2004



Ashwin D. Mehta, Ph.D.  
Primary Examiner  
Art Unit 1638